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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/005,889 | 11/07/2001 | Robert D. Black | 9099-4 | 7939 |

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EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|-----------------|------------------|--|
| Application No. | Applicant(s) | |
| 10/005,889 | BLACK, ROBERT D. | |
| Examiner | Art Unit | |
| Gary W. Counts | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 August 2004.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 8-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 8-17 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/27/04, 8/29/02, 10/07/01

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, Claims 8-17 in the reply filed on August 12, 2004 is acknowledged.

Information Disclosure Statement

2. Foreign Patent Documents DE 3219558A1, DE 3332075, and DE 4341903A1 listed on page 6 of the Information Disclosure Statement filed May 27, 2004 have not been considered because they are not in the English language, and no translation has been provided.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification does not disclose the signal is digitally encoded by the inductor as recited in claim 16. On page 13, line 33 – page 14 line 8 of the specification, Applicant discloses that the processor can provide an output E to a telemetry system (526). The telemetry system 526 can transmit/receive data to/from an ex vitro system. Applicant discloses that the transmitted/received data is digitally encoded. Applicant does not provide proper antecedent basis for “the signal is digitally encoded by the inductor”. The only disclosure of an inductor occurs on page 14, lines 15-19.

The specification does not disclose a biocompatible optical translucent layer as recited in claim 17.

Claim Objections

4. Claim 13 is objected to because of the following informalities: In claim 13, line 3 the recitation "couple" should be --coupled--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9, line 2 the recitation "a high powered LED" is vague and indefinite. It is unclear what applicant is referring to. Is applicant referring to intensity or voltage or something else? Further, it is unclear what is considered to be high.

Claim 16 is vague and indefinite because it is unclear what applicant intends. There is no description provided in the specification for the signal is digitally encoded via the inductor. It is unclear what the inductor is. Is applicant referring to a power source as indicated on page 14, lines 15-19 or is applicant referring to the telemetry system disclosed on page 14, lines 1-8 which can transmit/receive data which is digitally encoded or does applicant intend something else. Please clarify.

Claim 16, line 2 the recitation "via" is vague and indefinite. It is unclear what the term encompasses.

Claim 16, line 2 the recitation "the inductor" is vague and indefinite. There is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs et al (US 5,833,603).

Kovacs et al disclose a circuit comprising Light emitting diodes (LED's) (optical radiation source), a photosensor (optical radiation detector) and control circuitry (col 5, lines 1-27, col 11, line 44 – col 12, line 33). Kovacs et al disclose that this circuit can be configured for in vivo detection. Kovacs et al disclose that the photosensor can be photodiodes or phototransistors (col 2, lines 25-30).

With respect to the recitation "optical radiation emitted by excited labeled binding molecules" as recited in the instant claims. Since Kovacs et al teach the same circuit as recited, the circuit of Kovacs is capable of detecting excited labeled binding molecules and therefore, Kovacs anticipates the claims.

9. Claims 8, and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini, Jr. et al (US 6,551,838).

Santini, Jr. et al. disclose a circuit for in vivo applications. Santini, Jr. et al. disclose the circuit comprises a fiber optic which emits light (optical radiation source). Santini, Jr. et al also discloses that the fiber optic can detect and measures changes (optical radiation detector) in fluorescence or some other optical phenomenon. Santini, Jr. et al disclose control circuitry coupled to the fiber optic (col 9, lines 54-67, col 15, line 59 – col 16, line 43 and Figure 7). Santini, Jr. et al disclose coating or encapsulating all components of the circuit in a biocompatible material such as polyethylene glycol or metal or ceramic (col 9, lines 47-51 and col 15, lines 47-51). Santini, Jr. et al disclose the circuit is on a backing plate (platform) (col 17). Santini, Jr. et al disclose the device can be the size of a millimeter (col 4, lines 35-36). Santini, Jr. et al disclose that a transmitter (inductor) can be coupled to the circuit to transmit data and to control the circuit such as supplying power (col 6, lines 51-64).

With respect to the recitation “optical radiation emitted by excited labeled binding molecules” as recited in the instant claims. Since Santini, Jr. et al teach the same circuit as recited, the circuit of Santini, Jr. et al is capable of detecting excited labeled binding molecules and therefore, Santini, Jr. et al anticipates the claims.

With respect to the inductor as recited in the instant claims. Examiner has interpreted the transmitter of Santini, Jr. et al to be an inductor because it is unclear from the recited claims and specification what the inductor is. For example on page 14, lines 15-19, applicant discloses an inductor provides power to the in vivo system via an

inductively coupled power signal from the ex vitro system. On page 13, line 33 - page 14, line 8 applicant discloses the processor can provide an output E to a telemetry system (526). The telemetry system 526 can transmit/receive data to/from an ex vitro system. In claim 14, applicant recites "an inductor coupled to the processor, wherein the inductor provides power to the circuit in response to a power signal received from the ex vivo system. In claim 16, applicant recites "the signal is digitally encoded via the inductor". Since it is unclear if the "inductor" performs both tasks as claimed or if applicant has two separate inductors that perform the two claimed tasks. The examiner has interpreted the inductor as the telemetry system as shown in Figure 5 of applicant's disclosure. From Figure 5 and the description of Figure 5 provided in the specification the telemetry system provides for data and also provides for a signal from ex vivo to provide power to the circuit and since Santini, Jr. et al teach a transmitter which provides the same function as the telemetry system of the instant applicant. Examiner has interpreted the inductor to be the telemetry system and therefore, Santini, Jr. et al anticipates the recited claims.

10. Claims 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Crowley (US 6,343,227).

Crowley teaches a circuit comprising a light source (optical radiation source) and a light detector (optical radiation detector). Crowley teaches that the light source illuminates a substance and the detectors detect optical properties of the illuminated substance by measuring modified light signals (col 2, lines 18-31) (Figure 1A). Crowley teaches the circuit comprises a modulator for modulating the light source and also

comprises an analog to digital converter and a microprocessor for spectral analysis (col 3, lines 34-57). Crowley teaches the light source may be a light emitting diode and the light detector may be a photodiode (col 2, lines 44-50). Crowley teaches the light source may be coupled to a filter (col 9, lines 8-11). Crowley teaches the light detector may be coupled to a filter (col 5, lines 20-48, Fig. 2A and Fig. 4).

With respect to the first frequency is greater than the second frequency as recited in the instant claims. This limitation depends on the label that is used, and the label is not part of the circuit and therefore, whether or not the first frequency is greater than the second frequency is irrelevant. Therefore, Crowley anticipates the instantly recited claims.

Conclusion

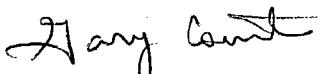
11. No claims are allowed.
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Van Antwerp et al. (6,750,311) disclose an implantable device that comprises a light source and a detector (Figure. 6). Van Antwerp et al disclose the use of a filtered LED and a filtered detector.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
September 16, 2004



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SUPERVISORY PATENT EXAMINER
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09/17/04